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COZEN O'CONNOR, P.C.			QUAN, ELIZABETH S	
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DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/678,434	<b>Applicant(s)</b> MCNEIL, JOHN	
	<b>Examiner</b> Elizabeth Quan	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25, 27, 28 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17, 23-25, 27, 28 and 31-34 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☒ Claim(s) 1-25, 27, 28 and 31-34 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the driving mechanism internal to the dispensing mechanism, dispensed volume replacement mechanism, storage device connected to a dispensing mechanism and comprising a multi-well plate, and positive displacement pump type dispensing mechanism along with the structure as recited in claims 10, 15, and 16 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

2. Claim 8 is objected to because of the following informalities: "an" before "dispensed volume replacement mechanism" should be "a". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10, 15, 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the structural elements constituting the positive displacement pump-type dispensing mechanism, does not reasonably provide enablement for the driving mechanism internal to the positive displacement pump-type dispensing mechanism. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Neither the drawings nor specification provide reasonable explanation of how the driving mechanism is internal to the positive displacement pump-type dispensing mechanism.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-8, 10-17, 23-25, 27, 28, 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the location of the filter with respect to the recited structural elements of the storage device(s), dispensing mechanism, and drive mechanism. Claim 1 is also rendered indefinite since the limitation "wherein said sample passes through a filter" is a method step in an apparatus/device claim.

8. Claims 15 and 16 are rendered indefinite since it appears the actuator and driving mechanism are referring to the same element. Reference character (25) of fig. 4 of the instant drawings is labeled "actuator drive mechanism (electromagnet)." Fig. 5 of the instant drawings further confuses the invention since reference character (35) is referred to as "actuator drive mechanism" and reference character (32) is referred to as "actuator (active)." Now, (32) appears to point at the cow udder and (35) points an object that is external to the driving mechanism.

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Reference character (31) points to the same element as reference character (32). The driving mechanisms of figs. 1 and 11a are not internal to the dispensing mechanism. The claims are not in scope with the various embodiments by taking various elements from each of the embodiments to produce quite an incomprehensible invention.

9. Claim 23 is rendered indefinite since it is unclear whether there is simply a lack of antecedent basis or there is another filter involved, in which case the filters should be designated a first filter and a second filter.

10. Claim 34 is rendered indefinite since it is unclear if the claim was actually meant for the presence of more than one robot since the robots have features for locating robots. It is unclear if these features are for locating the robot itself since parent claims only require one robot to meet the claim. What does “**autonomous** positioning and transferring features” and “**onboard** self-dispensing storage devices” mean?

***Claim Rejections - 35 USC § 102***

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,985,631 to Wannlund et al.

Wannlund et al. disclose a self-dispensing system (50) (fig. 5). The system comprises a first self-dispensing storage device (52), which has a storage device with a plurality of reservoirs for holding a sample to be dispensed and plurality of corresponding dispensing mechanisms (60) connected to and in dispensing communication with each of the reservoirs of the storage device, and a second self-dispensing storage device (24), which has a storage device with a plurality of

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reservoirs for holding a sample to be dispensed and plurality of corresponding dispensing mechanisms (40) connected to and in dispensing communication with each of the reservoirs of the storage device (fig. 5). The first self-dispensing storage device is positioned over the second self-dispensing storage device (fig. 5). The system also comprises a driving mechanism for driving the dispensing mechanism of the first self-dispensing storage device, such that a precise and reproducible measured volume of the sample is dispensed from the reservoirs of the first self-dispensing storage device to the reservoirs of the second self-dispensing storage device (figs. 5-10; col. 10, lines 10-39; col. 11, lines 44-col. 12, line 20).

13. Claims 1 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,874,971 to Nishioka et al.

Nishioka et al. disclose a self-dispensing system for dispensing a measured quantity or volume of a fluid (fig. 8). The system comprises a storage device (247), dispensing mechanism connected to the storage device, and a driving mechanism ~~247~~ internal to the dispensing mechanism (fig. 8; col. 9, lines 1-9). The storage device holds the fluid to be dispensed (col. 9, lines 1-9). The dispensing mechanism is in dispensing communication with the storage device for precisely dispensing a measured quantity of the fluid from the storage device upon actuation of the driving mechanism (col. 9, lines 1-9). The fluid passes through a filter (255), which is located between the storage device and dispensing mechanism (fig. 8; col. 9, lines 1-9). Note: The entire system, which includes the storage device, is disposable or can be thrown away.

***Claim Rejections - 35 USC § 103***

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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15. Claims 1-8, 10-14, 17, 24, 25, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,620,383 to Karg et al. in view of U.S. Patent No. 6,063,282 to Moulton or U.S. Patent No. 5,516,491 to Kath et al. or U.S. Patent No. 5,186,839 to Kimura et al.

Karg et al. disclose a self-dispensing system (10) for dispensing a measured quantity or volume of a sample (figs. 1-27). The system comprises a plurality of disposable storage devices, dispensing mechanism (25) connected to each of the storage devices, and driving mechanism (29) internal to the dispensing mechanism (figs. 1-27). The storage device is in the form of a multi-well plate, such that each of the wells of the multi-well plate has a corresponding dispensing mechanism (figs. 1-27). The multi-well plate appears to be a standard microtiter plate with 96 wells on even spaced centers (fig. 1). The dispensing mechanism is in dispensing communication with the storage device for precisely dispensing a measured quantity of sample from the storage device (col. 5, lines 35-43). The driving mechanism activates and drives the dispensing mechanism to dispense the sample since it draws sample within the dispensing mechanism and withdraws the sample from within the dispensing mechanism (col. 5, lines 25-53). The storage device and dispensing mechanism are disposable after the sample has been completely dispensed. Since the system may be made of stainless steel, polyethylene, or polypropylene, which are the preferred materials for fabricating the claimed invention as disclosed in the instant specification on page 13, lines 20 and 21, the self-dispensing storage device with its sample are freezable to at least about -20 degrees Celsius and is capable of being thawed and dispensed (col. 8, lines 1-5).

The storage device comprises a reservoir (21) for holding the sample to be dispensed (col. 5, lines 35-43). The reservoir has an upper and lower opening through which the dispensing mechanism reciprocates. When the side port (32) of the dispensing mechanism is in the reservoir and the driving mechanism is translated upward, liquid is drawn within the dispensing mechanism. When the dispensing mechanism is translated downward out of the reservoir through the lower opening of the reservoir and the driving mechanism is pushed downward, the liquid is forced out of the dispensing mechanism. The dispensing mechanism is translated upward into the reservoir through the lower opening for communicating another sample between the reservoir and dispensing mechanism (figs. 1-27). The dispensing mechanism is the reciprocating positive displacement pump type of dispensing mechanism, which is capable of precisely and reproducibly dispense a measured quantity of sample. Figs. 14 and 15 show an embodiment of the invention in which the size of the reservoir can be increased or decreased by movement of tube handle (26), such that the reservoir is collapsible. Regardless, given the right pressure, any reservoir is capable of collapsing or breaking down by changing shape or size. Since Applicant has not provided the structure of a cow udder, Examiner has defined a projection as a cow udder type of dispensing mechanism. In this case, the shape of the dispensing mechanism, which is a cylindrical projection, is characterized as a cow udder type of dispensing mechanism.

Karg et al. fail to disclose a filter through which a sample passes. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the self-dispensing system of Karg et al. with a filter to selectively provide movement of



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the sample by allowing the passage of fluid but not particles as necessary or desired as taught by Moulton or Kath et al. or Kimura et al.

Karg et al. fail to disclose the spacing and capacity of the wells. However, it is very well known that microtiter plates come in a variety of sizes with different well spacing to conform to automation and variety of capacities for dealing with a certain amount of samples, reactants, reagents, and generated products. Furthermore, it would have been obvious to one having ordinary skill in the art to modify the dimensions of the microtiter plate in order to conform to automation and deal with different amounts of samples, reactants, reagents, or generated products. It was held that different in dimensions is not a patentable distinction (*Gardener v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)) and discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)).

Since the dispensing mechanism can deliver 10 nanoliter amounts of fluid accurately and precisely with minimal or substantially zero dead volume via a metering tube that is translatable to the same position, it would appear that the dispensing mechanism could deliver a reproducible, measured quantity to an accuracy of about 5 microliters, 1 microliter, 0.5 microliter, and 0.1 microliter (col. 1, lines 50-65; col. 4, line 50-col. 5, line 13). Regardless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Karg et al. to provide the capability of dispensing to the above accuracies as necessary to handle a certain amount of samples, reactants, reagents, and generated products in performing certain assays.

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It appears that the storage device comprises a semi-rigid reservoir such that it is sufficiently durable to hold liquids. Karg et al. fail to disclose a dispensed volume replacement mechanism. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a dispensed volume replacement mechanism, such as a person or robot delivering liquids via a pipette or an automated delivery system delivering liquids in the apparatus of Karg et al. to replenish liquids to perform subsequent procedures or assays.

Karg et al. fail to disclose at least one robot for positioning the storage device with respect to another storage device or workstation. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide at least one robot in Karg et al. to efficiently and automatically position the storage devices with respect to each other such that the dispensing mechanism is operable between the two with easy and convenient access between the two. In the case of more than one robot, in order for the robot to position the storage devices they must be able to locate themselves as well as the storage devices. Furthermore, it has been held that providing mechanical or automatic means to replace manual activity, which accomplishes the same result, is within the skill of a routineer in the art (*In re Venner*, 120 USPQ 192 (CCPA 1958)).

16. Claims 1, 8, 10, 15, 16, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,976,470 to Maiefski et al. in view of U.S. Patent No. 6,063,282 to Moulton or U.S. Patent No. 5,516,491 to Kath et al. or U.S. Patent No. 5,186,839 to Kimura et al.

Maiefski et al. disclose a self-dispensing mechanism for dispensing a measured quantity or volume of a sample (figs. 1-20). The system comprises one or more disposable storage device

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(16) for holding fluids to be dispensed, dispensing mechanism (42) connected to each of the one or more storage devices, and driving mechanism (134) internal to the dispensing mechanism (figs. 1-20). The system is an automated system wherein support (34) is movable for positioning the self-dispensing storage device with respect to a workstation and a controller (26) for initiating a dispensing operation of the sample by the self-dispensing storage device (figs. 1-20). The storage device comprises a semi-rigid reservoir having a volume replacement mechanism for replacing a volume equal to a volume of the measured quantity of the dispensed fluid (col. 14, line 57-col. 15, line 60).

The dispensing mechanism is a reciprocating positive displacement pump-type dispensing mechanism (figs. 1-20). A selector valve (46) has rotary valve member (66) with an interior channel (70) positioned to communicate with the open bottom end (68) of only one solvent passageway (62) at a time depending on the selector valve's position (col. 9, lines 19-57). The selector valve's actuator (74) rotates the shaft (76) and the valve member to align the interior channel (70) with a selected solvent passageway (col. 9, lines 19-57). The actuator is connected to the controller (26), which activates the actuator to position the valve member in a desired position to allow the selected solvent to pass through the selector valve (col. 9, lines 19-57). The selector valve also has a gate valve (80) mounted in the bottom portion of the selector valves body (64) (col. 9, line 58-col. 10, line 15). The gate valve (80), which is partially positioned within the outlet passageway (72), is movable between the open and closed positions using an actuator similar to the actuator (74) described above (col. 9, line 58-col. 10, line 15). When the gate valve is in the open position, solvent can freely pass through the outlet passageway (72) into the distribution manifold (40) (col. 9, line 58-col. 10, line 15). When the gate valve is in the

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closed position, solvent is blocked from passing through the outlet passageway (72) into the distribution manifold (col. 9, line 58-col. 10, line 15). The gate valve includes a pressure relief passageway (73) that communicates with the outlet passageway (72) when the gate valve is in the closed position (col. 10, lines 3-15). The pressure relief passageway allows the release of back-pressure in the interior channel (72) to minimize back-pressure within the distribution manifold when the gate valve is in the closed passageway (col. 10, lines 3-15). Each distribution channel includes a ball-type check valve (104) that is movable between open and closed positions (col. 10, line 66-col. 11, line 20). In the open position, solvent flows from the upstream portion (110) and through and out the downstream portion (112) to the respective syringe aperture (100) (col. 10, line 66-col. 11, line 20). In the closed position, solvent is prevented from backflowing into the upstream portion (110) of the distribution channel (94) toward the manifold inlet (col. 10, line 66-col. 11, line 20). Note: It appears the claims are characterizing a single element as both the driving mechanism and actuator. See Figs. 4 and 5A of the instant drawings. The plunger has a suction stroke that draws a sample from the reservoir as the actuator moves in a first direction and discharge stroke that pushes the sample out as the actuator moves in the second direction (col. 13, line 31-col. 14, line 34). Nonetheless, each of the described valves has an actuator in an interrelated and interdependent manner capable of drawing a sample in a first direction and discharging a sample in a second direction.

Maiefski et al. fail to disclose a filter through which a sample passes. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the self-dispensing system of Maiefski et al. with a filter to selectively provide

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movement of the sample by allowing the passage of fluid but not particles as necessary or desired as taught by Moulton or Kath et al. or Kimura et al.

17. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,985,631 to Wannlund et al.

Wannlund et al. fail to disclose at least one robot for positioning the storage device with respect to another storage device or workstation. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide at least one robot in Wannlund et al. to efficiently and automatically position the storage devices with respect to each other such that the dispensing mechanism is operable between the two with easy and convenient access between the two. In the case of more than one robot, in order for the robot to position the storage devices they must be able to locate themselves as well as the storage devices.

Furthermore, it has been held that providing mechanical or automatic means to replace manual activity which accomplishes the same result is within the skill of a routineer in the art (*In re Venner*, 120 USPQ 192 (CCPA 1958)).

#### ***Response to Arguments***

18. Applicant's arguments with respect to claims 1-8, 10-17, 23-25, 27, and 28 have been considered but are moot in view of the new ground(s) of rejection.

19. Applicant's arguments, see pages 13 and 14, filed 11/17/2003, with respect to the rejection(s) of claim(s) 31-34 under Balch and Kenney have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wannlund et al.

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***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan  
Examiner  
Art Unit 1743

eq

  
Jill Warden  
Supervisory Patent Examiner  
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